

(3) A chest X-ray interpreted as negative for the existence of pneumoconiosis;

(4) A death certificate which makes no mention of pneumoconiosis.

APPENDIX A TO PART 718—STANDARDS FOR ADMINISTRATION AND INTERPRETATION OF CHEST ROENTGENOGRAMS (X-RAYS)

The following standards are established in accordance with sections 402(f)(1)(D) and 413(b) of the Act. They were developed in consultation with the National Institute for Occupational Safety and Health. These standards are promulgated for the guidance of physicians and medical technicians to insure that uniform procedures are used in administering and interpreting X-rays and that the best available medical evidence will be submitted in connection with a claim for black lung benefits. If it is established that one or more standards have not been met, the claims adjudicator may consider such fact in determining the evidentiary weight to be assigned to the physician's report of an X-ray.

(1) Every chest roentgenogram shall be a single postero-anterior projection at full inspiration on a 14 by 17 inch film. Additional chest films or views shall be obtained if they are necessary for clarification and classification. The film and cassette shall be capable of being positioned both vertically and horizontally so that the chest roentgenogram will include both apices and costophrenic angles. If a miner is too large to permit the above requirements, then a projection with minimum loss of costophrenic angle shall be made.

(2) Miners shall be disrobed from the waist up at the time the roentgenogram is given. The facility shall provide a dressing area and, for those miners who wish to use one, the facility shall provide a clean gown. Facilities shall be heated to a comfortable temperature.

(3) Roentgenograms shall be made only with a diagnostic X-ray machine having a rotating anode tube with a maximum of a 2 mm source (focal spot).

(4) Except as provided in paragraph (5), roentgenograms shall be made with units having generators which comply with the following: (a) the generators of existing roentgenographic units acquired by the examining facility prior to July 27, 1973, shall have a minimum rating of 200 mA at 100 kVp; (b) generators of units acquired subsequent to that date shall have a minimum rating of 300 mA at 125 kVp.

NOTE: A generator with a rating of 150 kVp is recommended.

(5) Roentgenograms made with battery-powered mobile or portable equipment shall

be made with units having a minimum rating of 100 mA at 110 kVp at 500 Hz, or 200 mA at 110 kVp at 60 Hz.

(6) Capacitor discharge, and field emission units may be used.

(7) Roentgenograms shall be given only with equipment having a beam-limiting device which does not cause large unexposed boundaries. The use of such a device shall be discernible from an examination of the roentgenogram.

(8) To insure high quality chest roentgenograms:

(i) The maximum exposure time shall not exceed $\frac{1}{20}$ of a second except that with single phase units with a rating less than 300 mA at 125 kVp and subjects with chest over 28 cm postero-anterior, the exposure may be increased to not more than $\frac{1}{10}$ of a second;

(ii) The source or focal spot to film distance shall be at least 6 feet;

(iii) Only medium-speed film and medium-speed intensifying screens shall be used;

(iv) Film-screen contact shall be maintained and verified at 6-month or shorter intervals;

(v) Intensifying screens shall be inspected at least once a month and cleaned when necessary by the method recommended by the manufacturer;

(vi) All intensifying screens in a cassette shall be of the same type and made by the same manufacturer;

(vii) When using over 90 kV, a suitable grid or other means of reducing scattered radiation shall be used;

(viii) The geometry of the radiographic system shall insure that the central axis (ray) of the primary beam is perpendicular to the plane of the film surface and impinges on the center of the film.

(9) Radiographic processing:

(i) Either automatic or manual film processing is acceptable. A constant time-temperature technique shall be meticulously employed for manual processing.

(ii) If mineral or other impurities in the processing water introduce difficulty in obtaining a high-quality roentgenogram, a suitable filter or purification system shall be used.

(10) Before the miner is advised that the examination is concluded, the roentgenogram shall be processed and inspected and accepted for quality by the physician, or if the physician is not available, acceptance may be made by the radiologic technologist. In a case of a substandard roentgenogram, another shall be made immediately.

(11) An electric power supply shall be used which complies with the voltage, current, and regulation specified by the manufacturer of the machine.

(12) A densitometric test object may be required on each roentgenogram for an objective evaluation of film quality at the discretion of the Department of Labor.

(13) Each roentgenogram made under this Appendix shall be permanently and legibly marked with the name and address of the facility at which it is made, the miner's DOL claim number, the date of the roentgenogram, and left and right side of film. No other identifying markings shall be recorded on the roentgenogram.

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APPENDIX B TO PART 718—STANDARDS FOR ADMINISTRATION AND INTERPRETATION OF PULMONARY FUNCTION TESTS. TABLES B1, B2, B3, B4, B5, B6.

The following standards are established in accordance with section 402(f)(1)(D) of the Act. They were developed in consultation with the National Institute for Occupational Safety and Health (NIOSH). These standards are promulgated for the guidance of physicians and medical technicians to insure that uniform procedures are used in administering and interpreting ventilatory function tests and that the best available medical evidence will be submitted in support of a claim for black lung benefits. If it is established that one or more standards have not been met, the claims adjudicator may consider such fact in determining the evidentiary weight to be given to the results of the ventilatory function tests.

(1) Instruments to be used for the administration of pulmonary function tests shall be approved by NIOSH and shall conform to the following criteria:

(i) The instrument shall be accurate within ± 50 ml or within ± 3 percent of reading, whichever is greater.

(ii) The instrument shall be capable of measuring vital capacity from 0 to 7 liters BTPS.

(iii) The instrument shall have a low inertia and offer low resistance to airflow such that the resistance to airflow at 12 liters per second must be less than 1.5 cm H₂O/liter/sec.

(iv) The instrument or user of the instrument must have a means of correcting volumes to body temperature saturated with water vapor (BTPS) under conditions of varying ambient spirometer temperatures and barometric pressures.

(v) The instrument used shall provide a tracing of flow versus volume (flow-volume loop) which displays the entire maximum inspiration and the entire maximum forced expiration. The instrument shall, in addition, provide tracings of the volume versus time tracing (spirogram) derived electronically from the flow-volume loop. Tracings are necessary to determine whether maximum inspiratory and expiratory efforts have been obtained during the FVC maneuver. If maximum voluntary ventilation is measured, the

tracing shall record the individual breaths volumes versus time.

(vi) The instrument shall be capable of accumulating volume for a minimum of 10 seconds after the onset of exhalation.

(vii) The instrument must be capable of being calibrated in the field with respect to the FEV₁. The volume calibration shall be accomplished with a 3 L calibrating syringe and should agree to within 1 percent of a 3 L calibrating volume. The linearity of the instrument must be documented by a record of volume calibrations at three different flow rates of approximately 3 L/6 sec, 3 L/3 sec, and 3 L/sec.

(viii) For measuring maximum voluntary ventilation (MVV) the instrument shall have a response which is flat within ± 10 percent up to 4 Hz at flow rates up to 12 liters per second over the volume range.

(ix) The spirogram shall be recorded at a speed of at least 20 mm/sec and a volume excursion of at least 10mm/L. Calculation of the FEV₁ from the flow-volume loop is not acceptable. Original tracings shall be submitted.

(2) The administration of pulmonary function tests shall conform to the following criteria:

(i) Tests shall not be performed during or soon after an acute respiratory illness.

(ii) For the FEV₁ and FVC, use of a nose clip is required. The procedures shall be explained in simple terms to the patient who shall be instructed to loosen any tight clothing and stand in front of the apparatus. The subject may sit, or stand, but care should be taken on repeat testing that the same position be used. Particular attention shall be given to insure that the chin is slightly elevated with the neck slightly extended. The subject shall be instructed to expire completely, momentarily hold his breath, place the mouthpiece in his mouth and close the mouth firmly about the mouthpiece to ensure no air leak. The subject will then make a maximum inspiration from the instrument and when maximum inspiration has been attained, without interruption, blow as hard, fast and completely as possible for at least 7 seconds or until a plateau has been attained in the volume-time curve with no detectable change in the expired volume during the last 2 seconds of maximal expiratory effort. A minimum of three flow-volume loops and derived spirometric tracings shall be carried out. The patient shall be observed throughout the study for compliance with instructions. Inspiration and expiration shall be checked visually for reproducibility. The effort shall be judged unacceptable when the patient:

(A) Has not reached full inspiration preceding the forced expiration; or

(B) Has not used maximal effort during the entire forced expiration; or